REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on June 29, 2005, the Examiner rejected claims 1, 4-12, 24 and 26 under 35 U.S.C. § 103(a) as being unpatentable over Mumford, Lou, "*Benefits of noni juice may be imagined; $30 price tag isn't: MUM'S THE WORD,*" SOUTH BEND TRIBUNE C1 (Feb. 20, 1998) ("Mumford") in view of Brock, Thomas D. et al, BIOLOGY OF MICROORGANISM 334 (6th ed. 1991)("Brock"), in view of Gagnon, Daniel J, LIQUID HERBAL DROPS IN EVERYDAY USE 22, 27 (3d. ed. 1997) ("Gagnon"), and further in view of Associated Press, *Another Study Indicates Soy Protein May Help Treat hot Flashes*, BUFFALO NEWS (Nov. 1996)("Buffalo News"). Accordingly, Applicant respectfully provides the following.

Claim Rejections under 35 U.S.C. § 103(a).

For the reasons set forth below, Applicant submits that the prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner. Thus, Applicant's claims are not obvious in view of the prior art references.

Applicant has amended the claims to include a blueberry juice concentrate. The prior art references cited by the Examiner alone or in combination with each other do not teach or suggest all the claim limitations of the presently amended claims. Claim 1 and claim 9 include limitations for consuming a supplement comprising: (1) *Morinda citrifolia* juice, (2) processed *Morinda citrifolia* pulp, (3) blueberry juice concentrate, and (4) a second juice. None of the cited references, alone or in combination with other cited references, discloses or suggests consumption of a *Morinda citrifolia*-containing supplement to inhibit, prevent and reverse lipid peroxidation. Second, none of the cited references, alone or in combination with other cited

references, discloses or suggests combining the *Morinda citrifolia* juice with processed *Morinda citrifolia* pulp and blueberry juice concentrate. Third, none of the cited references, alone or in combination with other cited references, discloses or suggests combining *Morinda citrifolia* fruit juice and at least one second juice from a group consisting of fruit juice and vegetable juice and blueberry juice concentrate. Consequently, the present invention is not obvious in view of such references because none of the prior art cited, alone or in combination with each other, teach or suggest all of the claim limitations of the present invention.

First, no cited reference alone or in combination with other cited references discloses or suggests the consumption of *Morinda citrifolia* containing a supplement to inhibit, prevent and reverse lipid peroxidation. Mumford discloses consuming *Morinda citrifolia* fruit juice to treat migraine headaches, increase energy levels and inhibit susceptibility to the common cold. Mumford also discloses topically applying *Morinda citrifolia* leaves to reduce pain. (See Mumford, p. 1-2). Mumford neither discloses nor suggests consuming *Morinda citrifolia* fruit juice to inhibit, prevent or reverse lipid peroxidation.

Inhibition of lipidperoxidation is not merely an intrinsic property of *Morinda citrifolia.* For example, TNJ (Tahitian Noni ® Juice) out performed other noni based juices in antioxidant studies performed in connection with this application. U.S. Provisional Pat. App. No. 60/251,417 contains the results of these experiments is incorporated by reference in the present application and attached for your convenient reference. Accordingly, the method of making the juice and the various constitutive elements added to the juice before delivery may have a significant effect on lipidperoxidation inhibition. Accordingly, the levels of lipidperoxidation inhibition experienced by utilizing the products and methods of the present invention are not merely intrinsict properties of *Morinda citrifolia.*

Second, no cited reference teaches administering *Morinda citrifolia* juice in combination with processed *Morinda citrifolia* pulp. In fact, the office action mailed May 20, 2003 indicated that Mumford taught the administration of juice alone, "[i]t is further deemed that because the article recited 'juice' that the juice was 100% *M. citrifolia* juice." Accordingly, Mumford teaches away from combining *Morinda citrifolia* juice with either the pulp or a second juice.

As noted above in conjunction with the research detailed in U.S. Provisional Pat. App. No. 60/251,417 the addition of the elements of the dietary supplement of the present invention are not merely a preference issue. Whether one like pulp in their juice is certainly an issue of taste preference, but the addition of pulp and other ingredient do impart increased efficacy as demonstrated by the above mentioned research.

Third, no cited reference discloses or suggests the consumption of a supplement containing *Morinda citrifolia* juice, blueberry juice concentrate and at least one second juice from the group consisting of fruit juice and vegetable juice. Buf falo News does not teach combining *Morinda citrifolia* juice, blueberry juice and another juice. Rather Buffalo News teaches mixing a dried powder with a liquid (e.g., orange juice or cereal milk) so the dried powder could be ingested. Mumford does not teach combining *Morinda citrifolia* juice with a second juice. Rather Mumford suggests that drinking *Morinda citrifolia* juice is a bad idea because it is overpriced and tastes bad. Further, as indicated above Mumford teaches consuming juice that is 100% *M. citrifolia* juice. Consequently, Mumford teaches away from consuming *Morindia citrifolia* juice in combination with a second juice

As the cited references fail to disclose or suggest all of the claim limitations of independent claims of the present invention, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

As claims 4-12, 24 and 26 depend from otherwise allowable subject matter, such claims are also not obvious in view of the cited references. Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1, 4-12, 24 and 26 under Section 103.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 29 day of September, 2005.

Respectfully submitted,

Michael F. Krieger
Attorney for Applicant
Registration No. 35,232

KIRTON & McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111
(801) 328-3600

JRM/sp
841054

Antioxidant Studies on TNJ

Principle: Active oxygen species (oxygen-containing molecules) present in human body mainly by the aspiration system. Active oxygen species attack lipids, sugars, proteins, and DNA and induce their oxidation, which may result in oxidative damage such as deterioration of foods, membrane dysfunction, protein modification, enzyme inactivation, and break of DNA strands and modification of its bases.

Tests: In our lab, we have tested TNJ ' s and competitor juices ' antioxidant activities towards active oxygen species (oxygen-containing molecules): superoxide anion radicals and lipid hydroperoxides.

Results:

a. TNJ is an antioxidant to both superoxide anion radicals and Lipid hydroperoxides.

b. TNJ antioxidant activities are comparable to vitamin C (2.28 times), pycnogenols (1.32 and 1.48 times to two different products), and grape seed powder (1.13 times)-these are well known antioxidants to superoxide free radicals-at their suggested daily intake amount.

c. TNJ antioxidant activities rank top of competitor juices.

7/12/00 3:52:02 PM . Page 1 of 2 Lipid Hydroperoxide Test

Instrument Serial Number EL97063594
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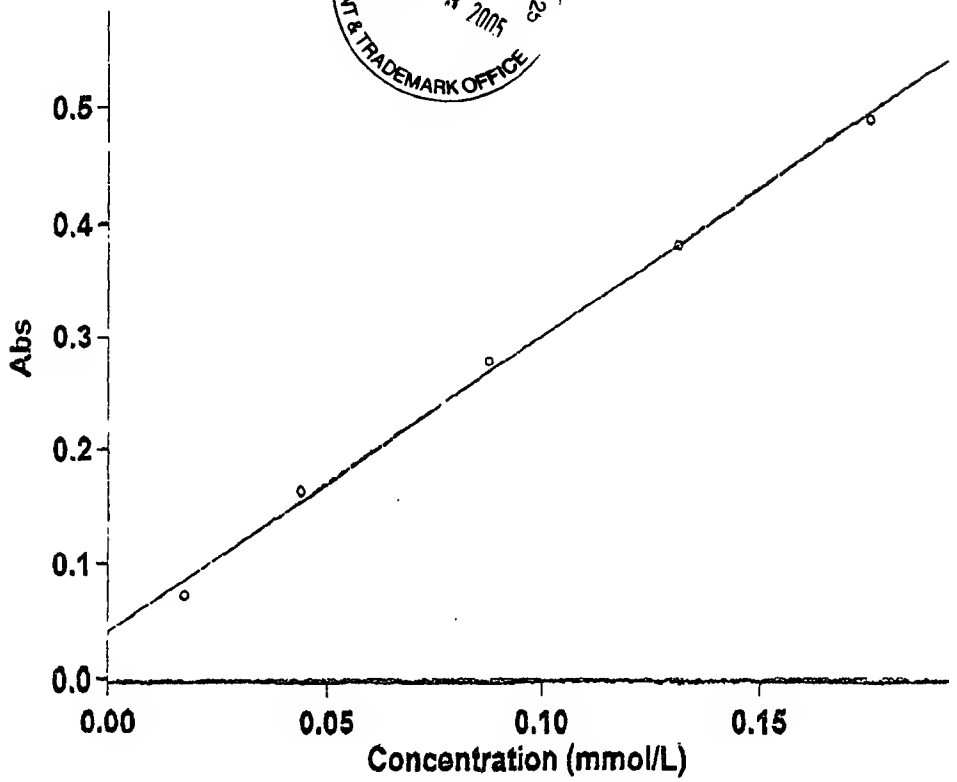


Analysis

Collection time 7/12/00 3:00:36 PM

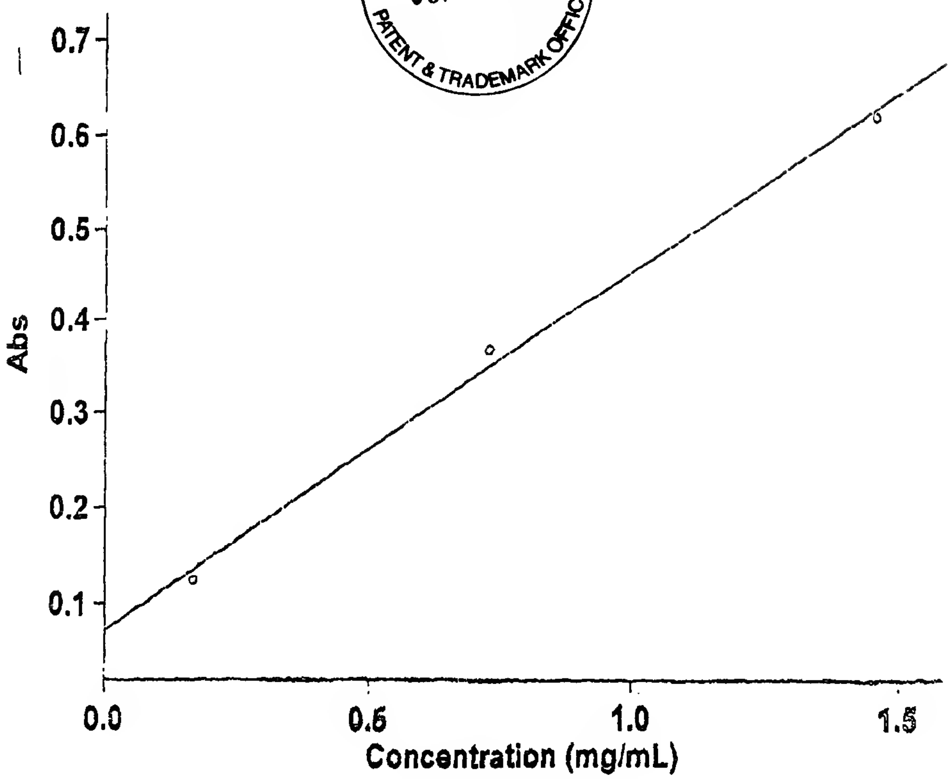
Sample	Concentration mmol/L	F	Readings
10ulStandard	0.198185	O	0.5542
0.25 Dose TNJ	0.073693		0.2312
0.5 Dose TNJ	0.053699		0.1793
1 Dose TNJ	0.042774		0.1510
1.5 Dose TNJ	0.034053		0.1284
2 Dose TNJ	0.029612		0.1168
2.5 Dose TNJ	0.027856		0.1123
3 Dose TNJ	0.026341		0.1084
10ul Standard	0.214405	O	0.5963
0.25 Dose TNJ	0.070917		0.2240
0.5 Dose TNJ	0.055804		0.1848
1 Dose TNJ	0.043239		0.1522
1.5 Dose TNJ	0.031284		0.1212
2 Dose TNJ	0.027536		0.1115
2.5 Dose TNJ	0.025697		0.1067
3 Dose TNJ	0.024458		0.1035

Results Flags Legend

U = Uncalibrated O = Overrange
N = Not used in calibration R = Repeat reading

 TNB test

Instrument Serial Number EL97063594
Instrument Serial Number EL97063594
Instrument Serial Number EL97063594



Analysis

Collection time 5/16/00 4:25:28 PN

Sample	Concentration mg/ml	F	Readings	
Sample 1	1.7299	O	0.7315	30 ul of NADH 20 ml/ml
Sample 2	0.3861		0.2184	Pycnogenol (New food)
Sample 3	0.5366		0.2759	Pycnogenol (Twinlab)
Sample 4	0.1676		0.1350	Grapeseeds.
Sample 5	0.7463		0.3559	puree
Sample 6	0.2056		0.1495	PM10
Sample 7	1.0767		0.4821	BITS
Sample 8	0.1569		0.1309	TNJ96
Sample 9	-0.0745		0.0425	TNJ97
Sample 10	-0.0791		0.0408	TNJ98
Sample 11	-0.0580		0.0488	TNJ99
Sample 12	-0.0397		0.0558	TNJ 2000
Sample 13	0.9551		0.4356	Ascorbic Acid.

Results Flags Legend

U = Uncalibrated
N = Not used in calibration
O = Overrange
R = Repeat reading

$$\frac{\text{TNJ 2000}}{\text{Pycnogenol New foods}} = \frac{0.6751}{0.5131} = 1.32$$

$$\frac{\text{TNJ 2000}}{\text{Pycnogenol Twinlab}} = \frac{0.6751}{0.4558} = 1.48$$

$$\frac{\text{TNJ 2000}}{\text{Grapeseeds}} = \frac{0.6751}{0.5965} = 1.13$$

$$\frac{\text{TNJ 2000}}{\text{Ascorbic Acid}} = \frac{0.6751}{0.2951} = 2.28$$

Lipid Hydroperoxide Assay

Principle: Cumen hydroperoxide oxides leucomethylen blue (LMB) to methylene blue which Absorbs UV light at 660 nm. Antioxidants reduce the absorbency by reacting with Cumen hydroperoxide.

Experiment:

Chemicals:

LMB-Leucomethylene blue, TCI America, 1-800-423-8616.
Cumen hydroperoxide, Sigma.
Triton X-100, Sigma.
Hemoglobin, Sigma.
Potassium phosphate, monobasic, Sigma.
DMF-N,N-Dimethyl-formamide, Sigma.

Equipment·

UV Spectrophotometer, VARIAN.

Procedure:

1. Dissolve 5 mg LMB in 8 ml DMF.
2. Make 0.05 M potassium phosphate buffer adjusted to pH 5.0 by 1% KOH.
3. Add 1.4 ml of triton X-100 and 5.5 mg of hemoglobin into 90.6 ml of buffer made in 2, mix well.
4. Mix solution 1 and 3.
5. Cumen hydroperoxide standard solution: dilute concentrated cumen hydroperoxide by 100 fold-0.0526 nmol/ul.
6. Standard curve: take 10 ul of standard solution in a 16x100 mm test tube, add 3 ml of solution 4 by pipetter, let it standard for 10 mins. Measure at 660 nm by UV spectrometer. Repeat this procedure for 20 ul, 30 ul, 40 ul, and 50 ul.
7. Sample preparation: take 40 ul of standard solution and add a certain amount of sample and repeat rest procedure as step 6.

TNB TEST
Superoxide Anion Radical Scavenger Effect Test

Principle: Superoxide anion radical (SAR) reduces tetrazolium nitroblue (TNB) into formazan blue, which absorbs UV light at 602 nm. SAR scavenger reduces the absorbency by reacting with SAR.
In this test, SAR is generated by NADH under aerobic condition and phenazine methosulfate (PMS) is used as a catalyst.

Experiment:

Chemicals:

NADH-b-Nicotinamide Adenine Dinucleotide Reduced Form, SIGMA, N 8129.
TNB-Tetrazolium Nitroblue or Nitroblue Tetrazolium, SIGMA, N6876.
PMS-Phenazine Methosulfate, SIGMA, P 9625.
Sodium pyrophosphate, SIGMA, S9515.
Concentrated Phosphoric Acid, SIGMA, P-6560

Equipment:

UV Spectrophotometer, VARIAN.

Procedure:

1. Buffer solution: dissolve 7.59 g of sodium pyrophosphate in 1 L of volumetric flask by DDI water-0.017 M. Adjust pH to 8.3 by concentrated phosphoric acid. Add 0.04g TNB—dissolve into solution and cover with foil or use an amber flask.

2. NADH standard solution: weigh 0.0400 g of NADH and dissolve it in 2 ml of DDI water (20mg/ml).

3. Weigh 0.0100 g of PMS and dissolve it in 10 ml of DDI water (1mg/ml).

4. Working Solvent: take a 100 ml of amber volumetric flask, add about 50 ml of solution 1 made in step 1), add 150 ul of PMS solution made in step 3, and add solution 1 to the marker. Make fresh daily.

5. Standard curve: take 10 ul of NADH standard solution in a 16x100 mm test tube, add 3 ml of working solvent by pipetter, and bubble oxygen air for 1 minute, keeping it the same speed for all samples. Measure at 602 nm by UV spectrometer. Repeat this procedure for 20 ul, 30 ul, 40 ul, and 50 ul of NADH standard solution.

6. Sample preparation: take 40 ul of NADH and add 21 ul of TNJ and repeat rest procedure as step 5.

7/12/00

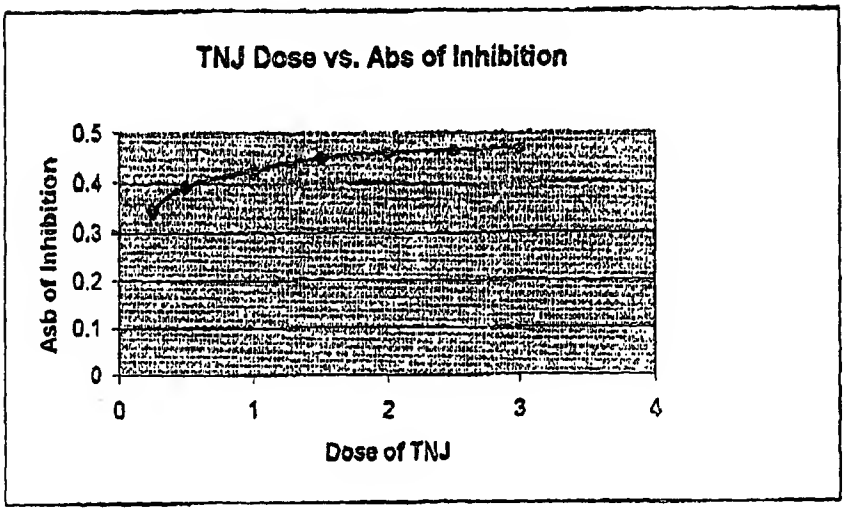
Dose Response Test

10 µL Standard of cumene hydroperoxide

0.25 Dose = 5 µL
0.5 Dose = 10 µL
1 Dose = 20 µL
1.5 Dose = 30 µL
2 Dose = 40 µL
2.5 Dose = 50 µL
3 Dose = 60 µL

TNJ Dose Level	Average Reading	Inhibition
0.25	0.2276	0.3477
0.5	0.1821	0.3832
1	0.1516	0.4237
1.5	0.1248	0.4505
2	0.1142	0.4611
2.5	0.1095	0.4658
3	0.1059	0.4694

10 ul Standard = 0.5753



Dose relationship is not linear as expected, but seems to level off as the amount of TNJ is increased.

7/15/00 TNJ Antioxidant Experiment. 5/16/00

Comparison of pycnogenol (Twinlab, NowFoods) groups

Calculation &

1. Sample digestions.

Twinlab: $\frac{30\text{ mg pycnogenol}}{0.3591\text{ g (per capsule)}} = 85\text{ mg pycnogenol/g}$.

NowFood: $\frac{30\text{ mg pycnogenol}}{0.3716\text{ g (per capsule)}} = 80.7\text{ mg pycnogenol/g}$.

Final concentration of amount of pycnogenol in 3ml of buffer solution $\Rightarrow \frac{60\text{ mg (suggested intake)}}{450\text{ml (Ave. body fluid)}}$

$= 0.0133\frac{\text{mg}}{\text{ml}} \times 3\text{ml} = 0.0$

Amount of sample needed = 20ul, Concentration of pycnogenol in Sample = M

$\frac{20\text{ ul}}{1000\text{ ul/ml}} \times M = 0.0399\text{ mg} = 1.995\text{ mg/ml}$ pycnogenol.

Sample will be dissolved in 100 ml of DDI H_2O. Amount of pyc.

$= 1.995\text{ mg/ml} \times 100\text{ ml} = 199.5\text{ mg}$

For Twinlab, amount of sample needed to be digested in order to have 199.5 mg of pycnogenol in 100 ml DDI H_2O:

$\frac{199.5\text{ mg}}{85\text{ mg/g}} = 2.347\text{ g}$ sample.

For NowFood:

$\frac{199.5\text{ mg}}{80.7\text{ mg/g}} = 2.47\text{ g}$ sample.

Grape seeds powder:

Daily Intake Suggested = 100 mg.

Final amount of grape seed in 3ml of buffer solution

$= \frac{100\text{ mg}}{450\text{ ml}} \times 3\text{ ml} = 0.667\text{ mg}$.

Amount of sample needed in experiment = 20 ul. Conc. of grap

5/16/00

$= M_1$.

$0.02\ ml \times M_1 = 0.667\ mg$, $M_1 = 33.35\ mg/ml$.

$33.35\ mg/ml \times$

Sample will dissolved in 100 ml DDI H_2O,

Amount of sample $= 33.35\ mg/ml \times 100\ ml = 3335\ mg$

Grape seeds powder is from DNP International Co. Inc. Batch# GSE-990601, 95% purity.

Therefore amount of sample = 351.05 mg.

2. See below for the experiments procedure. (revised)

C.Y.

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PMS-Phenazine Methosulfate, SIGMA, P 9625.
Sodium pyrophosphate, SIGMA, S6515.
Concentrated Phosphoric Acid, SIGMA, P-5550

Equipment:

UV Spectrophotometer, VARIAN.

Procedure:

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C.Y.S